

REMARKS

In the Office Action the Examiner rejected claims 45-49 under 35 USC § 103(a) as being unpatentable over **Wassenaar** (U.S. Patent No. 7,060,289) in view of the Merck Manual. Essentially, the Examiner observes that the Merck Manual teaches that athlete's foot, a fungus infection, commonly grows in warm moist areas between the toes. Further although **Wassenaar** does not teach a method for killing or inhibiting microorganisms including fungi, **Wassenaar** does disclose a case study of a patient wherein excessive sweating of the forehead and groin resulted in a rash and fungal infection. After **Wassenaar** used an anticholinergic amine to reduce the sweating, the chronic fungal infection and rash also improved. Therefore, the Examiner concludes that the combination of the Merck Manual (fungal infections develop in warm moist locations) with **Wassenaar** (excessive sweating may lead to fungal infections and reduction of such sweating causes improvement in the fungal infection) makes it obvious to use anticholinergic amines to inhibit growth of microorganisms including fungi.

Applicant respectfully traverses the Examiner's obviousness finding. The experiment reported by **Wassenaar** shows that reducing the availability of moisture (sweat) can lead to improvement in a fungal infection. This experiment does not demonstrate or suggest that ACQAs (such as glycopyrrolate) directly kill and inhibit microorganisms including dermatophytic fungi. By "directly" one means that the compound has a direct toxic biological effect as opposed to an indirect environmental effect such as by altering the growth environment (i.e., making things drier). Applicant has made the hitherto unknown and unexpected discovery that ACQAs, including glycopyrrolate kill (D-value) and inhibit (MIC) fungi and bacteria in *in vitro* tests. The Examiner is directed to paragraphs [0057] to [0063] of the specification. It is known that anti-fungal agents are widely sought; Applicant is the first to recognize the anti-fungal properties of this class of compounds. Applicant also recognizes the association of

fungus pathologies with warm and moist environments (see paragraph [0086]) pointed out by the Examiner and exemplified by Experiment 1 of **Wassenaar**. The direct killing and inhibition of microorganisms, including fungi, by ACQAs is above and beyond such a moisture reducing effect.

While it might be obvious to inhibit the growth of microorganisms by reducing the level of moisture (sweat) available in the growth environment (**Wassenaar**) Applicant respectfully points out that it was not obvious and was entirely unexpected to employ ACQAs as an agent to directly kill and inhibit fungi and other microorganisms. As shown in the Merck reference cited by the Examiner fungal infections (tinea corporis) can occur at any site on the body. Scalp and nail infections are pointed out as being particularly difficult to treat. Therefore, it is apparent that fungal infections are common on areas of the body that are generally not particularly moist. As demonstrated by Applicant's *in vitro* tests, ACQAs can kill or inhibit fungi (*Trichophyton*, a pathogen mentioned in the reference, was used in those *in vitro* tests). The ability of Applicant's inventive method to kill or inhibit fungal pathogens on dry parts of the body would not have been obvious in light of any of the cited prior art. Therefore, Applicant respectfully requests the Examiner to withdraw the rejections under 35 USC § 103 in view of **Wassenaar** be withdrawn.

Applicant respectfully suggests that the prior art does not anticipate or render obvious the use of ACQAs to kill directly and inhibit fungi. Since claim 45 is generic for the method of using ACQA's in this manner Applicant respectfully suggests that this claim be allowed as a generic claim encompassing glycopyrrolate.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested. If for any reason the Examiner still finds the application other than in condition for allowance, the Examiner is requested to call the undersigned

attorney at the Los Angeles telephone number (310) 229-9928 to discuss the steps necessary for placing the application in condition for allowance.

You are hereby authorized to charge any fees due and refund any surplus fees to our Deposit Account No. 22-0261. Please reference matter number 94902-256172.

Respectfully submitted,

VENABLE LLP

Date: 1-July-2008

By: /Stefan J. Kirchanski/
Stefan J. Kirchanski
Registration No. 36,568
Attorney for Applicant(s)

2049 Century Park East, 21st Floor
Los Angeles, CA 90067
Telephone: (310) 229-9900
Facsimile: (310) 229-9901
Email: SJKirchanski@venable.com